UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/579,230	09/28/2006	Robert J. Veldman	BJS-620-439	1300

23117 7590 10/01/2010

NIXON & VANDERHYE, PC
901 NORTH GLEBE ROAD, 11TH FLOOR
ARLINGTON, VA 22203

EXAMINER	
HENRY, MICHAEL C	

ART UNIT	PAPER NUMBER
1623	

MAIL DATE	DELIVERY MODE
10/01/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/579,230	VELDMAN ET AL.	
	Examiner	Art Unit	
	MICHAEL C. HENRY	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 June 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *92,94-134 and 136-146* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *125 and 126* is/are allowed.

6)☒ Claim(s) *92,99-105,108-121,123,124,127-131 and 136-146* is/are rejected.

7)☐ Claim(s) *94-98, 106, 107, 122, 132-134* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The following office action is a responsive to the Amendment filed, 06/01/10.

The amendment filed 06/01/10 affects the application 10/579,230 as follows:

1. Claims 92, 122, 125 and 146 have been amended. Claims 93, 135 and 147-151 have been canceled. Applicant's amendments and arguments have overcome the rejection made under 35 U.S.C. 112, second paragraph, under 35 U.S.C. 102(b) by applying Slotte et al. reference and under 35 U.S.C. 103(a) by applying the Higa et al. and Elias et al. references. However, the rejection made under 35 U.S.C. 103(a) by applying the Futerman et al. reference is maintained. A new ground(s) rejection is set forth herein below.
2. The responsive is contained herein below.

Claims 92, 94-134 and 136-146 are pending in application

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 92, 99-105, 108-121 and 123 are rejected under 35 U.S.C. 102(b) as being anticipated by Abe et al. (European Journal of Biochemistry (1992), 210(3), 765-73).

Claim 92 is drawn to a pharmaceutical formulation or composition comprising a amphiphilic drug and a short-chain sphingolipid having a given formula. Abe et al. disclose applicant's composition comprising a sphingolipid of said given formula ($GalCerSO_4$) and a drug

(stearoylpalmitoylglycerophosphocholine (StePamGroPCho) (see page 767, table 1, left col and abstract). It should be noted that Abe et al. disclose that their compound (GalCer) has a short chain acid (octanoyl) (see abstract). Claims 99, 100-105, 108-121 and 123 are also anticipated by Abe et al. since Abe et al.'s composition comprises a sphingolipid of said given formula ($GalCerSO_4$) and an amphiphilic drug (stearoylpalmitoylglycerophosphocholine (StePamGroPCho) (see page 767, table 1, left col. and abstract). Furthermore, Abe et al. disclose applicant's composition comprising a sphingolipid of said given formula (N-octanoylglycosylsphingosine (OctGlcSph)) and a drug (stearoylpalmitoylglycerophosphocholine (StePamGroPCho) (see page 767, table 1, left col. and abstract; see also page 766, left col., last paragraph, and page 769, table 4). Claims 99, 100-105, 108-121 and 123 are furhter anticipated by Abe et al. since Abe et al.'s composition comprises a sphingolipid of said given formula (OctGlcSph) and an amphiphilic drug (stearoylpalmitoylglycerophosphocholine (StePamGroPCho) (see page 767, table 1, left col. and abstract; see also page 766, left col., last paragraph, and page 769, table 4).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 124 is rejected under 35 U.S.C. 103(a) as being unpatentable over Abe et al. (European Journal of Biochemistry (1992), 210(3), 765-73).

Claim 124 is drawn to said pharmaceutical formulation or composition according to claim 92 wherein the short-chain sphingolipid having a specific given formula.

Abe et al. disclose applicant's composition comprising a sphingolipid of said given formula ($GalCerSO_4$) and a drug (stearoylpalmitoylglycerophosphocholine (StePamGroPCho) (see page 767, table 1, left col and abstract). It should be noted that Abe et al. disclose that their compound (GalCer) has a short chain acid (octanoyl) (see abstract). Furthermore, Abe et al. disclose applicant's composition comprising a sphingolipid of said given formula (N-octanoylglycosylsphingosine (OctGlcSph)) and a drug (stearoylpalmitoylglycerophosphocholine (StePamGroPCho) (see page 767, table 1, left col. and abstract; see also page 766, left col., last paragraph, and page 769, table 4). In addition, Abe et al. disclose applicant's short-chain sphingolipid compound (OctLacCer) having the said specific given formula (see page 768, left col. last paragraph). Also, Abe et al. disclose that OctSph is converted to OctGlcSph, OctLacCer, and short-chain sphingomyelin in OctSph-treated cells (see page 768, left col. last paragraph). Furthermore, Abe et al. disclose that glucosylceramide (GlcCer) has a potential role in growth promotion and hormonal signaling and in an effort to demonstrate a growth-promoting activity of GlcCer, Abe et al. prepared a GlcCer having a short-chain acid (octanoyl) which is combined with the specific lecithins, dioleoylglycerophosphocholine and 1-stearoyl-2-palmitoylglycerophosphocholine (see abstract). In addition, Abe et al. disclose that the octanoyl lipids and their anabolic products (OctLacCer, octanoyl gangliosides, etc.) may possible inhibited growth (see page 772, left col. next to last paragraph)..

The difference between applicants' claimed composition and the composition of Abe et al. is that applicant composition also contains an amphiphilic drug.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, to prepare a composition comprising a combination of Abe et al.'s compound (OctLacCer) and a drug such as the amphiphilic dioleoylglycerophosphocholine or 1-stearoyl-2-palmitoylglycerophosphocholine in order to use it to investigate or study whether or not Abe et al.'s compound (OctLacCer) has a potential role in growth promotion and hormonal signaling.

One having ordinary skill in the art would have been motivated in view of Abe et al. to prepare a composition comprising a combination of Abe et al.'s compound (OctLacCer) and a drug such as the amphiphilic dioleoylglycerophosphocholine or 1-stearoyl-2-palmitoylglycerophosphocholine in order to use it to investigate or study whether or not Abe et al.'s compound (OctLacCer) has a potential role in growth promotion and hormonal signaling.

Claims 92, 99-102, 105, 108-117, 127-131 and 136-146 are rejected under 35 U.S.C. 103(a) as being unpatentable over Futerman et al.(Methods in Enzymology (1992), 209(Phospholipid Biosynth.), 437-46).

Claim 92 is drawn to a pharmaceutical formulation or composition comprising a amphiphilic drug and a short-chain sphingolipid having a given formula. Dependent Claims 99-102, 105, 108-117 and 127-131, 135-146 are drawn to said composition comprising specific compounds of the said formula and specific formulations of said composition. Claim 146 is drawn to a liposome containing said composition

Futerman et al. disclose that a compound of the given formula which is a sphingolipid that bear a short-chain, radioactive fatty acid ([1-14C]hexanoic acid) can spontaneously transfer from either protein complexes or liposomes into biol. membranes without destroying membrane

integrity and have proven particularly useful for studies of sphingolipid metabolism in tissue fractions (see abstract). Futerman et al.'s compound has a Cas# of 143152-77-6 (see abstract).

The difference between applicants' claimed composition and the composition of Furterman et al. is that applicant composition also contains a drug.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, to prepare a composition comprising a combination of Futherman et al.'s compound and a drug such as a protein complex or liposome in order to use it to investigate or study the transfer of Futherman et al's compound from either protein complexes or liposomes into biological membranes without destroying membrane integrity and to study sphingolipid metabolism in tissue.

One having ordinary skill in the art would have been motivated in view of Futerman et al. to prepare a composition comprising a combination of Futherman et al.'s compound and a drug such as a protein complex or liposome in order to use it to investigate or study the transfer of Futherman et al's compound from either protein complexes or liposomes into biological membranes without destroying membrane integrity and to study sphingolipid metabolism in tissue. It should be noted that claims 99-102, 105, 108-117 and 127-131 which are limitations of claim 92 are also encompassed by this rejection as set forth above. It should also be noted that the preparation of different pharmaceutical formulations such as a liposomal formulation of active ingredients such said sphingolipid and antitumor drugs and excipients or adjuvants are common in the art and is well within the purview of a skilled artisan. Claims 94-98, 106, 107, 122 and 132-134 are objected to as being dependent on a rejected claim.

Response to Arguments

Applicant's arguments with respect to claims 92, 99-105, 134 and 136-146 have been considered but are not found convincing.

The applicant argues that Futerman et al. provides motivation to use certain short-chain spingolipids (e.g., "GlcCer" in Figure 1 therein) to study sphingolipid metabolism in vitro. However as set forth in the above rejection, Futerman et al. disclose that a compound of the given formula which is a sphingolipid that bear a short-chain, radioactive fatty acid ([1-14C]hexanoic acid) can spontaneously transfer from either protein complexes or liposomes into biol. membranes without destroying membrane integrity and have proven particularly useful for studies of sphingolipid metabolism in tissue fractions (see abstract). Futerman et al.'s compound has a Cas# of 143152-77-6 (see abstract). Consequently, one having ordinary skill in the art would have been motivated in view of Futerman et al. to prepare a composition comprising a combination of Futherman et al.'s compound and a drug such as a protein complex or liposome in order to use it to investigate or study the transfer of Futherman et al's compound from either protein complexes or liposomes into biological membranes without destroying membrane integrity and to study sphingolipid metabolism in tissue. It should be noted that Applicaqnt's claimed drug encompasses a protein complex or liposome that is disclosed by Futherman et al. Thus, Futerman et al. also provides motivation to use the said short-chain spingolipids with a drug such as such as a protein complex or liposome.

The Applicant argues that one of ordinary skill would not have made the claimed invention from the disclosure of Futerman et al. However, Futerman et al. disclose that a compound of the given formula which is a sphingolipid that bear a short-chain, radioactive fatty acid ([1-14C]hexanoic acid) can spontaneously transfer from either protein complexes or

liposomes into biol. membranes without destroying membrane integrity and have proven particularly useful for studies of sphingolipid metabolism in tissue fractions (see abstract). Futerman et al.'s compound has a Cas# of 143152-77-6 (see abstract). Consequently, one having ordinary skill in the art would have been motivated in view of Futerman et al. to prepare a composition comprising a combination of Futherman et al.'s compound and a drug such as a protein complex or liposome in order to use it to investigate or study the transfer of Futherman et al's compound from either protein complexes or liposomes into biological membranes without destroying membrane integrity and to study sphingolipid metabolism in tissue. It should be noted that Applicaqnt's claimed drug encompasses a protein complex or liposome that is disclosed by Futherman et al. Thus, Futerman et al. also provides motivation to use the said short-chain spingolipids with a drug such as such as a protein complex or liposome.

The Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8.30am-5pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael C. Henry
September 29, 2010.

/Shaojia Anna Jiang/
Supervisory Patent Examiner
Art Unit 1623